UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/050,249	03/30/1998	HARUKI OKAMURA	OKAMURA=2B	6601

1444 7590 11/01/2004

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/050,249	OKAMURA ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *93-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *93-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's response filed on 03 August 2004 is acknowledged.

Currently claims 93-120 are pending and under consideration.

Formal Matters:

The specification is objected to for the following informalities, appropriate correction is required for each item:

At page 9, lines 13-14, it is recited that "variants, which have complementary amino acid sequences to the one in SEQ ID NO:3, ...". The term "complementary amino acid sequence" is not a recognized term in the art. If the same recitation is present elsewhere in the specification, and applicants are required to make all corrections accordingly.

New Matter Rejection:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 93-96, 98-117 and 119 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last Office Action mailed on 11 February 2004, at pages 2-3.

Applicants argument filed on 03 August 2004 has been fully considered, but is not deemed persuasive for reasons below.

At pages 2-3 of the response, the applicant argues that applicants do not intend to cover antibodies which recognize some other protein having different antigenic fragments from (i) IGIF or IL-18 as defined in claim 93, and that the disclosures and teachings in the specification provide sufficient support for a monoclonal antibody which specifically recognizes (ii), a variant of (i), and has the same antigenic fragments to be used in obtaining said monoclonal antibody.

This argument is not persuasive because the issue is not whether applicants *intend to* cover antibodies which recognize some other protein, rather, the issue is that claim 93 (part (ii)), as amended, *reads on* a monoclonal antibody to a variant having the same antigenic fragment(s) as in (i), and the specification provides no concept of such a variant. The emphasized disclosure pointed out by applicants merely defines the variants as by replacing one or more amino acid in SEQ ID NO:3 without altering the inherent biological properties of the protein, which is not the same concept as that of a variant of (i), and has the same antigenic fragments because the variant defined in the specification does not have to have the same antigenic fragments as SEQ ID NO:3, and therefore, the disclosure in the specification does not support the amended limitation.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 94, 98-117 and 119 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the previous Office Actions, mailed on 20 May 2003, and 11 February 2004.

Applicants argument filed on 03 August 2004 has been fully considered, but is not deemed persuasive for reasons below.

At page 4 of the response, the applicant argues that claim 94 is dependent from claim 93, which includes more important limitations than the wash step, that limiting the temperature of the wash step is too restrictive because the wash step in the specification covers a wide range of temperatures from lower to higher stringency. This argument is not persuasive because although the independent claim 93 includes more important limitations than the wash step, it also encompasses the variants merely having the same antigenic fragments as SEQ ID NO:2 (part (ii)), and thus, the limitation in claim 94 includes the variants hybridizing to a variant in part (ii) of claim 93. As such, without reciting the washing temperature in the claim, which would affect the removal of nonspecific hybridization complexes, one cannot determine the metes and bounds of nucleic acids within the limitations of the claim.

The remaining claims remain rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 93-96 and 98-118 remain rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the reasons set forth in the previous Office Actions, paper Nos. 22, 24, 29 and 31.

Applicants argument filed on 03 August 2004 has been fully considered, but is not deemed persuasive for reasons below.

At pages 4-5 of the response, the applicant argues that the present invention is a so-called pioneering invention, which is directed to a monoclonal antibody recognizing a totally new substance, IL-18, and that therefore, broader protection should be given to the claimed invention. This argument is not persuasive because the present application merely discloses the IL-18 from one species, mouse IL-18, and it does not disclose what essential features define an IL-18 in a manner that supports the breadth of the claims. IL-18 from different distant species would have distinct sequence structures, and they are patentably distinct inventions, and are not predictable from one to the other.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 93-120 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* (*Infect. Immun.* 61: 64-70, 1993), for the reasons set forth in the previous Office Actions, paper No. 22, 24, 29 and 31, and the Office Action mailed on 11 February 2004.

Applicants argument filed on 03 August 2004 has been fully considered, but is not deemed persuasive for reasons below.

At pages 5-6 of the response, the applicant argues that Nakamura (1993) discloses nothing about a monoclonal antibody recognizing Nakamura's factor, and that it is quite uncertain from Nakamura's disclosure if such a monoclonal antibody can be actually obtained. This argument is not persuasive for the reasons addressed in the previous Office Actions, and reiterated below:

"Because Nakamura describes the protein of original claim 1, including its biological activity, a monoclonal antibody specific for that protein is obvious under 35 U.S.C.. 103 as a matter of law, per counsel's express concession.

To the extent that Nakamura is ambiguous as to the molecular weight and to the extent that claim 1 cannot be fairly construed to read on a material which is said to exhibit a molecular weight outside the recited range, counsel's concession nonetheless weighs in favor of the conclusion that the genus of monoclonal antibodies specific for the Nakamura IGIF material is obvious under. 103. In addition to conceding the obviousness of a mAb to "the protein of claim 1," counsel stated in the reply of 14 February 1997 that "[t]echniques of raising monoclonal antibodies are well known" and that "[k]nowing the biological activity of such protein [as the protein of claim 1], one of ordinary skill in the art would have been motivated to make a monoclonal antibody for the purpose of immunoaffinity chromatography or for the purpose of blocking its activity. The techniques for doing so are well known."

Regardless the reasons addressed by the Examiner in the previous Office Actions, the applicant repeatedly argues on page 6 of the response, that applicants believe that Nakamura's factor is not the same as IGIF because of different molecular weight revealed on SDS-PAGE and the gel filtration method. This argument is not persuasive for the reasons of record set forth in the previous Office Actions, i.e., IGIF in the serum sample (75 kDa) was the same IGIF as that

found in the liver extract (19 kDa), and the higher molecular weight form was considered to be bound to another protein or to exist in an oligomeric form.

At pages 6-7 of the response, the applicant further argues that even if Nakamura's factor comprises IGIF, the molecular weight of another protein is considered to be 56 kDa, about three times that of IGIF, that a skilled person would reasonably obtain monoclonal antibodies to the other protein rather than that to IGIF, and the monoclonal antibodies obtained would contain many kinds of antibodies, that therefore, it would require undue experimentation to obtain a monoclonal antibody recognizing Nakamura's IGIF, and that it would have been very difficult to obtain a monoclonal antibody to IGIF even if Nakamura's factor is an oligomer of IGIF, and it would undoubtedly prevent from obtaining the desired monoclonal antibody without undue experimentation because of the impurities of the protein. This argument is not persuasive because, as addressed in the last Office Action, the purity would not be a critical issue to prevent obtaining the monoclonal antibody to Nakamura's IGIF as the key step to obtain a monoclonal antibody is to isolate a single cell line (a hybridoma) producing the monoclonal antibody to IGIF, not that the protein has to be 100% homogenous. The technique to obtain such a cloned cell line had been well established and widely practiced at the time the present invention was filed.

Conclusion:

No claim is allowable.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Lorraine Spector

Dong Jiang, Ph.D.
Patent Examiner
AU1646
10/20/04